DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

Tanveer Ahmad, Ph.D.
Senior Director of Regulatory Affairs
Otsuka America Pharmaceutical, Inc.
Regulatory Affairs Department
2440 Research Boulevard
Rockville, MD 20850

NOV - 9 1998

RE:
Pletal (cilostazol) Tablets
MACMIS ID# 7254

Dear Dr. Ahmad:

Reference is made to Otsuka America Pharmaceutical, Inc.'s (Otsuka) November 3, 1998 letter to the Division of Drug Marketing, Advertising and Communications (DDMAC). This letter included a submission of draft promotional materials for Pletal (cilostazol), an investigational new drug. Reference is also made to a teleconference between Otsuka and DDMAC on November 6, 1998, during which DDMAC was informed by Otsuka that the "coming soon/walking women" journal advertisement (ID 5064), included in the above referenced submission, was being disseminated by Otsuka for the promotion of Pletal. DDMAC has reviewed this advertisement and has determined that it is in violation of the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations. Specifically, this journal advertisement promotes an unapproved new drug. Reference is also made to a September 17, 1998 letter from DDMAC, citing a journal advertisement (ID 5023) for Pletal that was in violation of the Act because it promoted an unapproved new drug.

Permissible coming soon advertisements announce the name of a new product that will be available soon, but do not make written, verbal, or graphic representations or suggestions concerning the safety, efficacy, or intended use of the product. In this "coming soon/walking women" journal advertisement, Otsuka presents the name of the investigational new drug, the statement "coming soon from Otsuka America Pharmaceutical, Inc.," and a picture of two women walking. This advertisement is not considered a "coming soon" advertisement because the picture of the two women walking makes a representation concerning the efficacy and intended use of Pletal,

In the November 6, 1998 teleconference, Otsuka was informed by DDMAC that it should immediately discontinue use of this journal advertisement and other promotional materials that

are similarly violative. Otsuka stated that it would immediately discontinue this advertisement, but that it would run in several journals due to publishing deadlines. In its November 6, 1998 letter, Otsuka provided the names of the journals containing the violative advertisement, and confirmed that it would not use a similar presentation (i.e., a poster) at the American Heart Association Meeting, November 9-11, 1998.

DDMAC is concerned that this is not the first instance where Otsuka has released violative promotional materials prior to the approval of Pletal. However, in light of actions taken by Otsuka in discontinuing this violative journal advertisement, and similar materials, DDMAC considers this matter closed. DDMAC will continue to closely monitor this issue.

If Otsuka has any further comments or questions, please address them to the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds Otsuka that only written communications are considered official.

In all future correspondence regarding the issues raised in this letter, please refer to MACMIS ID #7254 in addition to the NDA number.

Sincerely,

Janet Norden, MSN, RN
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications